



# Omnibus Final Rule Overview

NCVHS Full Committee

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# Omnibus Final Rule – What's New for Consumers

- HITECH Provisions:
  - Right to Electronic Copy of Electronic Health Record
    - Right to direct copy to designated 3d party
  - Prohibition on Sale of PHI without Authorization
  - Marketing Communications Paid for by 3d Party Require Authorization
    - Limited exceptions for refill reminders and current prescriptions
  - Requires Easy Way to Stop Fundraising Communications
  - Right to Restrict Disclosures to Health Plans of Treatment/Services Paid for in Cash

# Omnibus Final Rule – What’s New for Consumers

- GINA Provisions:
  - Requires “Genetic Information” be treated as PHI
  - Prohibits Health Plans from using/disclosing genetic information for underwriting purposes
  - Terms and definitions track regulations prohibiting discrimination in provision of health insurance based on genetic information

# Omnibus Final Rule – Non-statutory Provisions

- Student Immunization
  - **Makes it easier for parents to permit providers to release student immunization records to schools**
- Research
  - **Allows researchers to use single authorization for more than one research purpose**
  - **Relaxes policy on authorizations for future research**
- Notice of Privacy Practices
  - **Updates required to Notices of Privacy Practices**
  - **Relaxes distribution requirements for Health Plans**
- Decedent Information
  - **Protections limited to 50 years after death**
  - **Eases access to friends and families**

# Omnibus Final Rule – What's New for Business Associates

- BAs must comply with the technical, administrative, and physical safeguard requirements under the Security Rule; liable for Security Rule violations
- BA must comply with use or disclosure limitations expressed in its contract and those in the Privacy Rule; criminal and civil liabilities attach for violations
- BA definition expressly includes Health Information Organizations, E-prescribing Gateways, and PHR vendors that provide services to covered entities
- Subcontractors of a BA are now defined as a BA; clarifying that BA liability flows to all subcontractors

# Omnibus Final Rule – What’s New for Breaches and Enforcement

- **Breach Notification Provisions**
  - **Replaces “harm to individual” with more objective measure of compromise to the data as threshold for breach notification**
  - **Other provisions of 2009 IFR adopted without major change**
- **Enforcement Provisions**
  - **Adopts increased CMP amounts and tiered levels of culpability from 2009 IFR**
  - **Clarifies “Reasonable Cause” Tier**
  - **Willful Neglect cases do not require informal resolution**
  - **Intentional wrongful disclosures may be subject to civil, rather than criminal, penalties**

## Omnibus Final Rule – Important Dates

- Public Display at Federal Register – January 17, 2013
- Published in Federal Register – January 25, 2013
- Effective Date – March 26, 2013
- Compliance Date – September 23, 2013
- Conform BA contracts – September 22, 2014